# COUGH RELIEF NIGHTTIME- dextromethorphan hydrobromide, doxylamine succinate liquid QUALITY CHOICE (Chain Drug Marketing Association)

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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#### **Drug Facts**

#### Active ingredients (in each 30 mL)

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

# Purposes

Cough suppressant

Antihistamine

# Uses

temporarily relieves cold symptoms

- cough
- runny nose and sneezing

# Warnings

# Do not use

- to make a child sleepy
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

# Ask a doctor before use if you have

- a sodium-restricted diet
- asthma
- emphysema
- glaucoma
- chronic bronchitis
- excessive phlegm (mucus)
- breathing problems
- persistent or chronic cough
- cough associated with smoking
- trouble urinating due to enlarged prostate gland

# Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

# When using this product

• do not use more than directed

- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

#### Stop use and ask a doctor if

- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain or cough gets worse or lasts more than 7 days
- cough comes back or occurs with rash or headache that lasts

These could be signs of a serious condition.

# If pregnant or breast-feeding,

ask a health professional before use.

# Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) immediatly.

#### Directions

- take only as recommended
- do not exceed 4 doses per 24 hours
- use dosage cup provided
- mL = milliliter

| age                                 | dose                                   |  |  |
|-------------------------------------|--|--|--|
| adults & children 12 years and over | 30 mL every 6 hours                    |  |  |
| children 4 to 11 years              | do not use unless directed by a doctor |  |  |
| children under 4 years              | do not use                             |  |  |

• When using DayTime and Nighttime products, carefully read each label to ensure correct dosing

# Other information

- each 30 mL contains; sodium 36 mg
- store at room temperature

# **Inactive ingredients**

alcohol, citric acid, FD&C blue 1, FD&C red 40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

# Questions or comments?

# Call 1-248-449-9300 Monday-Friday 9AM-5PM EST

# **Principal Display Panel**

\*Compare to the active ingredients in VICKS® NYQUIL® Cough

# Nighttime Cough

# **Cough Relief**

Dextromethorphan HBr | Doxylamine Succinate

For Relief of:

cough | Runny Nose & Sneezing

For Ages 12 & Over

Alcohol 10 %

FL OZ (mL)

CHERRY FLAVOR

\*This product is not manufactured or distributed by Proctor & Gamble, owner of the registered trademark Vicks® NyQuil® Cough.

# TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

#### Failure to follow these warnings could result in serious consequences.

Distributed by C.D.M.A., Inc.©

43157 W. Nine Mile

Novi, MI 48376-0995

www.qualitychoice.com

# **Product** Label



Quality Choice NightTime Cough Relief

| Product Inform   | ation                     |  |                                  |                         |                     |                    |
|--|---------------------------|--|----------------------------------|-------------------------|---------------------|--------------------|
| Product T ype  |                           | HUMAN OTC DRUG   | Item Code (Source) NI            |                         | DC:63868-237        |                    |
| Route of Administ  | ration                    | ORAL   |                                  |                         |                     |                    |
|  |                           | _  |                                  |                         |                     |                    |
| Active Ingredie  |                           | 0  |                                  |                         |                     |                    |
| Ingredient Name  |                           |  | Basis of Strength                |                         | Strength            |                    |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9KYH)<br>(DEXTROMETHORPHAN - UNII:7355X3ROTS) |                           |  | DEXTROMETHORPHAN<br>HYDROBROMIDE |                         | 30 mg<br>in 30 mL   |                    |
| DO XYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DO XYLAMINE -<br>JNII:95QB77JKPL)                      |                           |  | DOXYLAMINE SUCCINATE             |                         | 12.5 mg<br>in 30 mL |                    |
| ·  | •                         |  |                                  |                         |                     |                    |
| Inactive Ingred  | ients                     | Ingradiant Name  |                                  |                         |                     | Strongth           |
| ALCOHOL (UNII: 31  | 29958 <u>7001</u> M       | Ingredient Name  |                                  |                         |                     | Strength           |
| ALCOHOL (UNII. SI<br>ANHYDROUS CITR  | ,                         | (E417D3DSI)  |                                  |                         |                     |                    |
| FD&C BLUE NO. 1  |                           |  |                                  |                         |                     |                    |
| FD&C BLUE NO. 1  |                           |  |                                  |                         |                     |                    |
| HIGH FRUCTOSE C  |                           |  |                                  |                         |                     |                    |
|  |                           | E <b>CIFIED</b> (UNII: 3WJQ0SDW1A)                         |                                  |                         |                     |                    |
|  |                           |  |                                  |                         |                     |                    |
| PROPYLENE GLYC   |                           | Q10773)  |                                  |                         |                     |                    |
| WATER (UNII: 059Q  |                           | IV 40 TV)  |                                  |                         |                     |                    |
| SACCHARIN SODIU  |                           |  |                                  |                         |                     |                    |
| I RISO DIUM CITRA  | I E DIHYDRAI              | E (UNII: B22547B95K)                                       |                                  |                         |                     |                    |
|  |                           |  |                                  |                         |                     |                    |
| Product Charac   | teristics                 |  |                                  |                         |                     |                    |
|  |                           |  | Score                            |                         |                     |                    |
| Color  | size                      |  |                                  |                         |                     |                    |
|  |                           |  | OILC                             |                         |                     |                    |
| Shape  |                           | CHERRY   | Imprint Code                     |                         |                     |                    |
| Shape<br>Flavor  |                           | CHERRY   |                                  |                         |                     |                    |
| Shape<br>Flavor  |                           | CHERRY   |                                  |                         |                     |                    |
| Shape<br>Flavor<br>Contains  |                           | CHERRY   |                                  |                         |                     |                    |
| Shape<br>Flavor<br>Contains<br>Packaging   |                           | CHERRY Package Description                                 |                                  | Marketing Start<br>Date | Mar                 | keting End<br>Date |
| Shape<br>Flavor<br>Contains<br>Packaging<br># Item Code  | 355 mL in 1 BO<br>Product |  | Imprint Code                     | •                       | Mar                 | -                  |
| Shape<br>Flavor<br>Contains<br>Packaging<br>I tem Code   |                           | Package Description  | Imprint Code                     | Date                    | Mar                 | -                  |
| Shape<br>Flavor<br>Contains<br>Packaging<br>I Item Code<br>NDC:63868-237-<br>12                  | Pro duc t                 | <b>Package Description</b><br>TTLE, PLASTIC; Type 0: Not a | Imprint Code                     | Date                    | Mar                 | -                  |
| 1 NDC:63868-237-   | Product                   | <b>Package Description</b><br>TTLE, PLASTIC; Type 0: Not a | Imprint Code<br>Combination      | Date<br>03/31/2016      |                     | -                  |

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 11/2019

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